

R E M A R K S

The outstanding Office Action of October 5, 2010 rejects Claim 18 under 35 U.S.C. 101, 35 U.S.C. 103 and under 35 U.S.C. 112. The application has been amended in response to the Examiner's comments and is now believed to be in condition for allowance.

Specifically, newly submitted independent Claim 19, Claim 18 in rewritten form, defines a classification and management system for patients with lower extremity arterial occlusive disease comprising a network of remotely located computers from healthcare facilities, an evaluating authority and accredited laboratory integrated to implement the steps on-line of:

- entering and storing the collected patient data of physically observable conditions of the patient's lower extremities and noninvasive arterial pressure and blood flow data in the memory of a computer at the healthcare facility,
- transmitting said collected patient data from the healthcare facility computer to a computer at an evaluating authority,
- receiving and storing the collected patient data in the computer at the evaluating authority to review and compare said collected patient data against a medically accepted set of disease specific criteria at the

evaluating authority to classify patients as "potentially at risk" and "not at risk" of developing complications of arterial occlusive disease,

- entering and storing patient classification data in the memory of the computer at the evaluation authority,
- transmitting said patient classification data from the evaluating authority computer to the computer at the healthcare facility,
- receiving and storing the patient classification data in the computer at the healthcare facility,
- transmitting the "potentially at risk" patient data from the healthcare facility to the accredited laboratory,
- entering and storing the "potentially at risk" patient data in a computer at an accredited laboratory to evaluate those "potentially at risk" patients at the accredited laboratory against medically accepted criteria,
- entering and storing the data results of said noninvasive vascular evaluation in the memory of the computer at the accredited laboratory,
- transmitting said stored data results from the accredited laboratory computer to the computer at the evaluating authority for final classification,
- receiving and storing the stored data results in the computer at the evaluating authority to classify each patient at the evaluating authority

against medically accepted criteria as "at risk" or "not at risk" of developing arterial occlusive disease,

- entering and storing patient classification in the memory of the computer at the evaluation authority,
- transmitting said "at risk" or "not at risk" patient final classification from the evaluation computer to the computer at the healthcare facility,
- entering and storing said "at risk" or "not at risk" patient final classification at the healthcare facility computer and transmitting data from the healthcare facility computer database having a final classification of "at risk" for critical ischemia with associated extremity lesions and patients with noninvasive evidence of severe ischemia to a vascular surgery facility for vascular surgical assessment to determine whether revascularization is necessary,
- reviewing the data and assessing such "at risk" patients against medically accepted criteria as "clinical indication for operation" or "no indication for operation" at the vascular surgery facility,
- electing revascularization and periodic management system evaluation at the healthcare facility or routine wound care and periodic revaluation at the healthcare facility by patients assessed as "clinical indication for operation",

- monitoring patients assessed as “no indication for operation” by the healthcare facility with increased precautions to monitor for detection of any visible deterioration of the patient’s lower extremities that would require reassessment,
- referring patients having ulcers, pain or gangrene at the time of “no indication for operation” assessment for reassessment,
- referring patients classified as “no indication for operation” that develop ulcers, pain and/or gangrene to the vascular surgery facility for reassessment,
- reassessing the referred patient at the vascular surgery facility against medically accepted criteria as “no indication for operation” or “clinical indication for operation”,
- entering and storing the reassessment in a memory of a computer at the vascular surgery facility,
- transmitting the reassessment of “no indication for operation” or “clinical indication for operation” from the vascular surgery facility computer to the computer at the evaluating authority for reevaluation as “no indication for operation” or “clinical indication for operation”,
- transmitting the reevaluation from the evaluating authority computer to the computer at the healthcare facility with the appropriate medical procedure and regimen for treating and monitoring patients classified as

“not at risk”, “at risk” and assessed as “no indication for operation” or “clinical indication for operation” at the healthcare facility,

- receiving and storing patient treatment and progress data in the memory of the computer at the healthcare facility to provide “not at risk” patients without limb ulcers routine care and precautions at the healthcare facility, “not at risk” patients with limb ulcers routine wound care at the healthcare facility and providing “not at risk” patients with limb ulcers periodic reevaluation by the evaluating authority,
- entering and storing the periodic patient reevaluations in the memory of the computer at the evaluating authority to provide “at risk” patients assessed as “no indication for operation” or “operation not elected by patient”, and “clinical indication for operation” patient undergoing revascularization at the vascular surgery facility with intensive wound care at the healthcare facility,
- entering and storing patient treatment and evaluation of patients in the memory of the computer at the vascular surgery facility,
- transmitting the patient treatment and evaluation data of patients from the vascular surgery facility to the healthcare facility,
- receiving and storing the patient treatment and evaluation data of patients in the computer at the healthcare facility,

- recording periodic reevaluations of "at risk" patients data assessed as "no indication for operation" or "operation not elected by patient" with increased precautions at the healthcare facility.

The Amendment is intended to address Examiner Rines' comments relating to the product versus process issue. Regarding Crutchfield, Applicant reiterates the complete invention of the subject application prior to the relevant data of Crutchfield. Accordingly, Applicant respectfully requests Examiner Rines' reconsider the Section 103 rejection.

In view of the amendments contained herein and the discussion in support thereof, allowance of this application is respectfully requested.

Notwithstanding, in the event that this response does not completely and fully address the matters and issues set forth in the outstanding Office Action, Examiner Rines is invited to contact Applicant's attorney by telephone in order to expeditiously conclude this prosecution.

Respectfully submitted,



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